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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/651,685	08/30/2000	Peter A. Ward	UM-04594	2029

23535 7590 12/15/2003

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EXAMINER	
VANDERVEGT, FRANCOIS P	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 12/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/651,685	WARD ET AL.	
	Examiner	Art Unit	
	F. Pierre VanderVegt	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 September 2003 and 25 September 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,3 and 5-7* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,3 and 5-7* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *25 September 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Claims 2 and 4 have been canceled previously.

Claims 1, 3 and 5-7 are currently pending and are the subject of examination in the present Office Action.

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on September 22, 2003 has been entered.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

2. Claims 1, 3 and 5-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "said symptoms" in line 7. There is insufficient antecedent basis for this limitation in the claim. While the claim earlier recites the word "symptoms," there are no symptoms enumerated in the claim and therefore there are no "said" symptoms. It is suggested that Applicant amend the claim to delete the word "said," or to recite symptoms of sepsis to be treated.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3, 5 and 6 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 4,686,100 to Raffin et al (A on form PTO-892; of record).

Applicant's arguments filed September 22, 2003 have been fully considered but they are not persuasive. The claims have been amended to recite treating a human patient for sepsis by administering a therapeutic composition comprising an antibody, wherein said antibody consists of an antibody specific for SEQ ID NO: 5. SEQ ID NO: 5 is disclosed by the specification to be a fragment of the human C5a complement component consisting of amino acid residues 21-40 of human C5a (SEQ ID NO: 3; page 26, Table 1 in particular). The specification further defines the term "specific for" at page 10, lines 21-25 thus:

> "The term "specific for" when used in reference to the interaction of an antibody and a protein or peptide means that the interaction is dependent upon the presence of a particular structure (i.e., the antigenic determinant or epitope) on the protein; in other words the antibody is recognizing and binding to a specific protein structure rather than to proteins in general (i.e. non-specific or background binding)."

The '100 patent teaches the treatment of human patients with sepsis comprising the administration of antibodies to C5a (see entire specification, column 3, lines 8-26 in particular). While the '100 patent is silent regarding antibodies reactive specifically with SEQ ID NO: 5, silence about a property does not necessarily constitute its absence. The '100 patent teaches the immunization of animals with the 74 amino acid C5a peptide to generate antibodies, while the present specification discloses immunization with a 20 amino acid fragment of the C5a peptide. One of skill in the art would recognize that the full-length C5a peptide would inherently possess the particular structure, including antigenic determinants or epitopes therein, of SEQ ID NO: 5. Absent evidence that immunization with full-length C5a would not generate antibodies to the truncated form, the antibody preparation obtained by the method of the '100 patent would inherently contain antibodies that bind to SEQ ID NO: 5, as all antigenic determinants within the full-length human C5a, including SEQ ID NO: 5, would be available to the immune system of the immunized animal for the generation of epitope-specific antibodies.

Despite Applicant's amendment and assertion to the contrary the instant claim is still drafted in an open format. The recitation of "a therapeutic composition comprising an antibody, wherein said antibody consists of an antibody specific for SEQ ID NO: 5" specifies that antibodies to the SEQ ID NO: 5 region of human C5a (SEQ ID NO: 3) must be present in the composition, not that antibodies to other antigenic determinants or epitopes of human C5a cannot be present. It is respectfully submitted that the artisan would recognize that immunization with full-length human C5a would generate antibodies to the truncated form. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are

directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). In regard to instant claim 5, the '100 patent teaches the production of polyclonal antibodies to human C5a at column 3, line 50 to column 4, line 20 in particular. In regard to instant claim 6, the '100 patent teaches that monoclonal antibodies to human C5a can be "produced by means well known in the art" at column 3, lines 43-47 in particular. The prior art reference anticipates the claimed invention.

4. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 102(b) as being anticipated by EP 0 245 993 (14 on form PTO-1449; of record).

The claims have been amended to recite treating a human patient for sepsis by administering a therapeutic composition comprising an antibody, wherein said antibody consists of an antibody specific for SEQ ID NO: 5. SEQ ID NO: 5 is disclosed by the specification to be a fragment of the human C5a complement component consisting of amino acid residues 21-40 of human C5a (SEQ ID NO: 3; page 26, Table 1 in particular). The specification further defines the term "specific for" at page 10, lines 21-25 thus:

> "The term "specific for" when used in reference to the interaction of an antibody and a protein or peptide means that the interaction is dependent upon the presence of a particular structure (i.e., the antigenic determinant or epitope) on the protein; in other words the antibody is recognizing and binding to a specific protein structure rather than to proteins in general (i.e. non-specific or background binding)."

The '993 publication teaches the treatment of human patients with sepsis comprising the administration of monoclonal antibodies to C5a (page 3, lines 1-47 and page 5, lines 1-48 in particular). While the '993 publication is silent regarding antibodies reactive specifically with SEQ ID NO: 5, silence about a property does not necessarily constitute its absence. The '993 publication teaches the immunization of animals with the 74 amino acid C5a peptide to generate antibodies, while the present specification discloses immunization with a 20 amino acid truncation of the C5a peptide. One of skill in the art would recognize that the full-length C5a peptide would inherently possess the particular structure, including antigenic determinants or epitopes therein, of SEQ ID NO: 5. Absent evidence that immunization with full-length C5a would not generate antibodies to the truncated form, the antibody

preparation obtained by the method of the '993 publication would inherently contain antibodies that bind to SEQ ID NO: 5, as all antigenic determinants within the full-length human C5a, including SEQ ID NO: 5, would be available to the immune system of the immunized animal for the generation of epitope-specific antibodies.

Despite Applicant's amendment and assertion to the contrary the instant claim is still drafted in an open format. The recitation of "a therapeutic composition comprising an antibody, wherein said antibody consists of an antibody specific for SEQ ID NO: 5" specifies that antibodies to the SEQ ID NO: 5 region of human C5a (SEQ ID NO: 3) must be present in the composition, not that antibodies to other antigenic determinants or epitopes of human C5a cannot be present. It is respectfully submitted that the artisan would recognize that immunization with full-length human C5a would generate antibodies to the truncated form. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that there is a difference between the materials, i.e., that the claims are directed to new materials and that such a difference would have been considered unexpected by one of ordinary skill in the art, that is, the claimed subject matter, if new, is unobvious. In the absence of evidence to the contrary, the burden is on the Applicant to prove that the claimed materials are different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989). In regard to instant claim 7, the '993 publication teaches that the monoclonal antibodies of that invention are able to bind C5a in the presence of a molar excess of C5 (page 3, lines 36-39, page 9, lines 1-31 and Table II in particular). The prior art reference anticipates the claimed invention.

Conclusion

5. No claim is allowed.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to F. Pierre VanderVegt whose telephone number is (703) 305-4441. The examiner can normally be reached on M-Th 6:30-4:00; Alternate Fridays 6:30-3:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (703) 308-3973.

Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of papers must conform with the notice published in the Official Gazette,

1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-3014.Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

As of January 7, 2004, the Examiner's telephone number will be (571) 272-0852.

F. Pierre VanderVegt, Ph.D.
Patent Examiner
December 10, 2003

PATRICK J. NOLAN, PH.D.
PRIMARY EXAMINER
12/11/03